Syrup. FDA is also declaring all identical, similar, and related drug products, not otherwise subject to an approved drug application, unlawful, including Brofed Tablets and Hydroxyzine Compound Syrup. Each of these products contains theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. The basis of the withdrawals is that there is a lack of substantial evidence that these combination drugs are effective for the treatment of bronchial asthma.

EFFECTIVE DATE: August 7, 1998.

ADDRESSES: Requests for applicability of this notice to a specific product should be identified with the Docket and DESI numbers found in brackets in the heading of this document and directed to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: As part of the agency's drug efficacy program, in a notice published in the **Federal Register** of September 17, 1984 (49 FR 36443), the Commissioner of Food and Drugs granted an evidentiary hearing before an administrative law judge on the proposal to withdraw approval of NDA 11–768 for Marax Tablets and NDA 12–879 for Marax Syrup, each containing theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. The NDA's are held by J. B. Roerig, Division of Pfizer, Inc. (Pfizer), 235 East 42d St., New York, NY 10017.

Other party participants were:

1. Barre-National, Inc., 4128 Haywood Ave., Baltimore, MD 21215 (Barre); Hydroxyzine Compound Syrup (no NDA).

2. Cord Laboratories, Inc. (now Geneva Pharmaceuticals, Inc.), 2555 West Midway Blvd., Broomfield, CO 80038 (Cord); Brofed Tablets (no NDA).

3. Barrows Research Group, Inc., 99 West Hawthorne Ave., Valley Stream, NY 11580 (Barrows). Unnamed drug product. Barrows later withdrew its hearing request.

Subsequently, in accordance with agreements to resolve, by other means, the issue of their drug products' effectiveness, Pfizer, Barre, and Cord withdrew their hearing requests. Under those agreements, FDA has concluded that Marax Tablets and Marax Syrup have not been shown to be effective, and FDA is now withdrawing approval of the NDA's for these products.

This notice applies to any drug product that is identical, related, or similar to these products and is not the subject of an approved NDA (21 CFR 310.6). Such products include Hydroxyzine Compound Syrup and Brofed Tablets, each of which contains theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and under the authority delegated to her (21 CFR 5.82), finds that on the basis of new information before her with respect to Marax Tablets and Marax Syrup, evaluated together with the evidence available to her when the applications were approved, there is a lack of substantial evidence that the products will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approvals and all the amendments and supplements thereto of NDA 11–768 and NDA 12–879 are withdrawn effective August 7, 1998. Shipment in interstate commerce of the products listed above or of any identical, related, or similar product that is not the subject of an approved NDA will then be unlawful.

Dated: June 15, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–18140 Filed 7–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appears in the **Federal Register** of June 25, 1998 (63 FR 34655). The notice announced a meeting of the Anti-Infective Drugs Advisory Committee, which was scheduled for July 29, 30, and 31, 1998. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Carolyn C. Harris, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

In FR Doc. 98–16934 appearing on page 34655 in the **Federal Register** of Thursday, June 25, 1998, the following correction is made:

On page 34655, under the *Agenda* caption, in the 2d column, beginning in the 1st line, ''http://www.fda.gov/cder/guidance.htm'' is corrected to read ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: July 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–18144 Filed 7–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Notice of Hearing: Reconsideration of Disapproval of New York Title XXI State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on July 29, 1998; 10:00 a.m., Thirty-Eighth floor, 26 Federal Plaza, New York, New York 10278 to reconsider our decision to disapprove New York Title XXI SPA.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by July 23, 1998.

FOR FURTHER INFORMATION CONTACT: Stan Katz, Presiding Officer, HCFA, C1–09–13, 7500 Security Boulevard, Baltimore, Maryland 21244, Telephone: (410)–786–2661.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove the New York Title XXI State Plan Amendment (SPA) submitted March 26, 1998.

Section 1116 of the Social Security Act (the Act) and 42 CFR Part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. These requirements are made applicable under